

SOP#: RPS-14

Submission of the Personal Financial Holdings Form to the Institute/Center Deputy Ethics Counselor

Version #: 2.1

Next Review Date: 05/2024

Approved Date: 05/2022

Review Interval Period: Biennial

NCI Clinical Director Signature:

POLICY

Assessment of financial conflict of interest is required for all clinical research protocols that may lead to the financial benefit or loss of any individual or entity. All staff involved in a research study are required to disclose financial and other conflicts of interest per NIH policy.

PURPOSE

To identify the process for submitting the Personal Financial Holdings (PFH) form via iRIS to the Deputy Ethics Counselor (DEC) for review. This process is performed by the Protocol Support Office (PSO) manager assigned to the protocol.

RESOURCES

NIH Office of Intramural Research Policies [website](#)

- Policy 102 – Investigator Conflict of Interest and Government Royalties
- Policy 300 – Investigator Responsibilities

PROCEDURES

STEP 1: Preparation Prior to Submitting Personal Financial Holdings (PFH) Form

- Review NIH Policy 102 noted above prior to submission of the PFH form to the Institute Deputy Ethics Counselor (DEC) office of the protocol Principal Investigator (PI) or NIH Ethics Office (NEO), if applicable.
- Confirm with the PI if the protocol is “covered.” Only studies that are “covered” require submission of the PFH to the DEC office.
- Confirm with the PI the “covered” Key Study Personnel (KSP) that will be participating in the protocol. The PI must designate those individuals who are conducting human subjects research (e.g., “engaged”) on the protocol (e.g., Associate Investigators (AIs), Adjunct PIs, Lead Associate Investigators (LAIs), or Medical Advisory Investigators (MAIs), as applicable), and list them on the KSP and IRB application.

Note: IRB has indicated that non-engaged individuals (e.g., collaborators) should not be listed on the IRB application. However, CCR PSO policy is to list these individuals on our KSP List for tracking purposes.

- Send the Conflict of Interest (COI) guide to all engaged individuals serving as KSP on the protocol via the study correspondence in iRIS or email (if via email, save the email in the study working file).

Note: This is only required to be sent once to each AI (i.e., when first added to the study).

- Send the COI Certification document: “COI Certification for Non-NIH Federal Employees and NIH Employees Who Do Not File a Financial Disclosure Report” to engaged investigators who are non-NIH federal employees or NIH federal employees who do not file financial disclosure forms. This form is generally used for staff with a classification of “Fellow” in NIH Enterprise Directory (NED) and non-NIH federal employees (e.g., FDA, Walter Reed).
- Send the COI Certification document: “COI Certification for Non-Federal Employees” to non-NIH AIs on the protocol.

STEP 2: Personal Financial Holdings Submission for Initial Review

- Complete the required fields in the study application in iRIS.
- Complete the “DEC Clearance Submission Form” in iRIS. This is the iRIS name for the Personal Financial Holdings Form.
- Attach the clean KSP list, the study application and the signed and dated COI certification form(s), if applicable.
- Submit the form for DEC review. The DEC form does not require PI signature for submission.
- You will receive the DEC Clearance back via iRIS from the DEC. Save the DEC Clearance in the working file and attach this document to the IRB submission in iRIS. Update the “Initial Review Submission Form” with the DEC approval date.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.

STEP 3: Personal Financial Holdings Submission for Amendments

- Any amendment involving the addition of or modification to any covered personnel on a covered protocol, a change in role of an individual from a non-covered to a covered role, any changes related to the use of commercial products, or any change to an IND/IDE requires the submission of the PFH to the DEC for review. Confirm changes with the PI.

Note: If you are only removing an individual(s) from a KSP list, a DEC review is not required.

- Send the COI guide to new individuals being added as KSP on the protocol via the study correspondence in iRIS or email (if via email, save the email in the study working file).
- Obtain COI Certification, if applicable, from new KSP who do not file financial disclosure forms and/or from non-NIH employees serving in covered roles, as described above in Step 1.
- Attach the clean and tracked KSP list, the study application and the COI certification forms, if applicable.

- If you are submitting a PFH to the DEC for a KSP addition (amendment) or a combined Continuing Review (CR) and amendment, you will need to:
 - Create a new DEC clearance form in iRIS.
 - Click on “add investigator” to navigate to the screen where you indicate the individuals you are adding/removing
 - Include the individuals you are adding/removing
- Submit the form for DEC review. The DEC form does not require PI signature for submission.
- You will receive the DEC Clearance back via iRIS from the DEC. Save the DEC Clearance in the working file for the applicable action and attach this document to the IRB submission in iRIS.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.

STEP 4: Personal Financial Holdings Submission for Continuing Review (CR)

- Submit the DEC Clearance request at the same time as the request for CR information is sent to the study team, as DEC clearance could delay CR approval.

Note: New COI certification forms are needed for each applicable KSP at time of CR for involved AIs who have not signed a form within the 6 months prior to study expiration.

- Check that current KSP list matches the list of Key Study Personnel in iRIS.

Note: If you need to remove someone in order for the DEC to be cleared (e.g., staff member is no longer at the institution), you will need to submit a concurrent amendment to the KSP. Review the amended KSP list with the PI. Also, remember to check the box for “CR/Amendment/KSP Changes” on the type of action on the DEC Clearance submission form.
- Complete DEC Clearance submission form in iRIS and include copy of KSP list, COI certification forms (signed/dated, if applicable), and the study application
- Submit the form for DEC review. The DEC form does not require PI signature for submission.
- You will receive the DEC Clearance back via iRIS from the DEC. Save the DEC Clearance in the working file and attach this document to the IRB submission in iRIS and update the “Progress Report Form” with the DEC approval date.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.